

## REMARKS/ARGUMENT

### **Description of Amendments**

Applicants have amended claims 19-23, 28, 29, 34, 59, 64, and 70; rewritten claims 18 and 27 in independent form; and cancelled claim 17. As amended, claims 18-23 and 25-80 are pending and under examination.

### **Rejection under 35 U.S.C. §112, Second Paragraph**

Claim 17 was rejected under 35 U.S.C. §112, second paragraph, on the ground that the limitation “pores” lacks antecedent basis. Although this rejection has been rendered moot by the cancellation of claim 17, Applicants wish to point out that the limitation “porous surface” inherently has pores and therefore provides antecedent basis for the limitation “pores.” *Manual of Patent Examination Procedure*, 8th Ed., Rev. No. 5, §2173.05(e) (2006) (“[i]nherent components of elements recited have antecedent basis in the recitation of the components themselves”).

### **Rejections under 35 U.S.C. §102**

Claims 17, 27-29, and 34 were rejected under 35 U.S.C. §102(e) as being anticipated by *Taylor* (U.S. Patent 6,214,115). The cancellation of claim 17 renders its rejection moot. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 27-29 and 34.

Regarding independent claim 27, Applicants respectfully submit that *Taylor* does not teach at least the limitation that “the pores have an open end and a closed end so as to provide a closed pore system on the surface of the mounting assembly” (emphasis added).

The Examiner contended that column 3, lines 23-26, of *Taylor* discloses the closed pore system of claim 27. According to the Examiner, *Taylor* teaches that “a sheath is placed around the external periphery of the support member and the sheath has one or more spiral slots formed around its outer surface (col. 3, line 23-26), thus providing a closed pore system on the porous surface.”

Applicants respectfully disagree with the Examiner's reading of *Taylor*, because the "pores" described in *Taylor* are open pores. The paragraph of *Taylor*, which includes column 3, lines 23-26, is reproduced below:

"FIG. 3 shows an alternative support member 3 in which the support member 3 is formed from a rigid hollow tube having one or more slots 12 formed in a surface and parallel to its axis. A sheath 13, formed from a plastics material, ceramic, or other appropriate material is placed around the external periphery of the support member 3. The sheath 13 has a plurality of apertures 14, or may have one or more spiral slots formed around its outer surface. This arrangement also defines apertures through which air can be drawn in use."

The above paragraph clearly states that the support member 3 includes a hollow tube and a sheath 13 placed around the hollow tube. The tube has one or more slots 12, and the sheath 13 may have one or more spiral slots. The slots 12 of the tube and the spiral slots of the sheath 13 define apertures through which air can be drawn. Since the pores defined by the slots 12 and spiral slots are used to draw air through the support member 3, they must be through pores. Since the spiral slots of the sheath 13 are used to define through pores, they must be open.

It should be noted that the fact that the spiral slots are described as being formed around the outer surface of the sheath 13 does not necessarily indicate that the slots are closed. In *Taylor* open slots or apertures are described as being formed on a surface. For example, *Taylor* discloses that the apertures 11 shown in Figure 2 are formed on the surface of the support member 3 (column 3, lines 12-13). *Taylor* also discloses that the apertures 11 allow passage of air from the exterior of the support member 3 through to its hollow interior (column 3, line 13-14). This clearly shows that the apertures 11, although described as formed on a surface of the support member 3, are open.

In conclusion, *Taylor* does not anticipate claim 27 because it does not teach the closed pore system of claim 27.

The rejection of claim 28 is now moot because claim 28 has been amended to depend from claim 18.

Regarding amended claim 29, Applicants respectfully submit that *Taylor* does not teach the limitation that "the absorbing layer is in contact with an end of the stent during the application of the coating composition." In *Taylor*, the stent is mounted on the ring members

15 (Figure 1). Therefore, the stent ends cannot be in contact with the sheath 13, which the Examiner considered as an absorbing layer.

Regarding amended claim 34, *Taylor* does not teach the limitation that “the absorbing material is in contact with an end of the stent during the application of the coating composition.” In *Taylor*, as stated above, the ends of the stent cannot be in contact with the sheath 13, which the Examiner considered as an absorbing material.

Claims 53 and 55-58 were rejected under 35 U.S.C. §102(e) as being anticipated by *Moein* (U.S. Patent 6,572,644). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Attached to this Amendment is a Declaration under 37 C.F.R. §1.131, which establishes invention by Applicants prior to the filing date of *Moein*. Therefore, *Moein* is not prior art to the claimed invention under 35 U.S.C. §102(e).

Claims 17, 18, 20-23, 25, 26, 39, and 47-52 were rejected under 35 U.S.C. §102(e) as being anticipated by *Heller* (U.S. Patent Publication 20030215564). The cancellation of claim 17 renders its rejection moot. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 18, 20-23, 25, 26, 39, and 47-52.

Among the rejected claims, claims 18 and 39 are the only independent claims. Each of independent claims 18 and 39 recites a first member of the mounting assembly contacting a first end of the stent and a second member of the mounting assembly contacting a second end of the stent.

*Heller* does not disclose two members contacting the two ends of the stent, respectively. In *Heller*, the stent is mounted on a single member (i.e., the balloon 304 shown in Figure 7). Accordingly, *Heller* cannot anticipate independent claims 18 and 39. Dependent claims 20-23, 25, 26, and 47-52 are also not anticipated because they depend from independent claims 18 and 39.

Additionally or alternatively, independent claim 18 recites that “pores [of the mounting assembly] are configured to receive at least some of the coating composition applied to the stent,” and independent claim 39 recites “a porous surface capable of receiving some of the coating composition.”

The Examiner did not contend that *Heller* expressly teaches the pores and porous surface of independent claims 18 and 39. Instead she contended that the catheter balloon 304 of *Heller*, on which the stent 306 is mounted during coating, functions as a stent support and inherently has a porous surface that is capable of receiving excess coating solution.

To establish inherency, the missing limitation (i.e., the pores or porous surface in this case) must be necessarily present in the reference, and it would be so recognized by persons of ordinary skill in the art. *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). Inherency may not be established by probabilities or possibilities. *Id.*

Applicants respectfully submit that the Examiner has not established, under the above-described test, that *Heller* inherently discloses the pores and porous surface of independent claims 18 and 39. The Examiner contended that *Heller* teaches that the catheter 302 can carry fluid into or out of the body, and seemed to suggest that this implies that the balloon of the catheter has a porous surface. Applicants respectfully disagree. The fact that the catheter 302 of *Heller* carries fluid into or out of the body does not mean that the catheter balloon 304 necessarily has a porous surface. It is quite possible that the fluid enters or exits the catheter 302 through a pore not on the balloon 304. It is also possible that the catheter 302 does not have a pore and the fluid merely enters or exits the body to inflate or deflate the balloon 304 without exiting the catheter 302. These possibilities demonstrate that the catheter balloon 304 of *Heller* does not inherently have a porous surface.

The Examiner also stated that “[t]he porous surface of the balloon is well established in the art of using with a stent for enabling the flow of fluids with respect to the stent.” Applicants are not quite sure what this statement is meant to convey. Assuming that the statement is meant to say that a porous surface of a balloon for use with a stent is well established in the art, the statement, if accurate, merely establishes that *Heller’s* balloon 304 may have a porous surface. It does not establish that *Heller’s* balloon 304 necessarily has a porous surface. Therefore, the statement does not establish that *Heller’s* balloon 304 inherently has a porous surface.

It should be noted that *Heller’s* balloon 304 is used to deploy the stent in a blood vessel (see *Heller* at paragraphs [0003], [0065], [0115] and [0120]). During a medical procedure, the catheter-stent assembly is advanced in the blood vessel to the site of obstruction, and the balloon 304 is expanded to deploy the stent in its proper position (see

*Heller* at paragraphs [0115] and [0120]). It is often desirable to have a balloon without a porous surface, because a porous balloon is difficult or impossible to inflate. Consequently, it is very likely that *Heller's* balloon 304 does not have a porous surface.

In conclusion, *Heller* does not expressly or inherently teach the pores and porous surface of independent claims 18 and 39. Therefore, *Heller* cannot anticipate independent claims 18 and 39. Dependent claims 20-23, 25, 26, and 47-52 are also not anticipated because they depend from independent claims 18 and 39.

Claims 64-66 and 70-72 were rejected under 35 U.S.C. §102(e) as being anticipated by *Parsons* (U.S. Patent 6,521,284). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Among the rejected claims, claims 64 and 70 are the only independent claims. Independent claim 64 recites that “a surface of the third member [of a mounting assembly] includes pores that receives a portion of the coating composition that comes in contact with the surface of the third member during the application of the coating composition.” Independent claim 70 recites that “the third member includes an absorbing layer or is made from an absorbent material that at least partially absorbs some of the coating composition that comes in contact with the third member during the application of the coating composition.”

The Examiner did not specifically address claim 64's pores. Regarding the absorbing layer (or absorbent material) of claim 70, the Examiner contended that *Parsons* discloses a porous mandrel made of a porous polymeric material and that the mandrel's porous polymeric material “inherently would be able to absorb some of the coating material” (emphasis added).

Applicants respectfully disagree with the Examiner's reading of *Parsons*. As shown in Figure 2, *Parsons* discloses an apparatus for impregnating a porous material 6 with a composition 14. The composition 14 is disposed in a cavity 16 defined by the porous material 6, a hollow mandrel 2, and two spacers 4a, 4b. During the impregnating process, a pressurized gas enters the interior of the mandrel 2 and then passes through the pores 12 of the mandrel 2 into the cavity 16. The pressurized gas in the cavity 16 compresses the composition into the porous material 6.

*Parsons* teaches that “[d]esirably, the mandrel 2 may have openings 12 which are micropores that permit passage of gases but do not permit passage of other materials, such as the cross-linkable composition 14” (see column 5, first paragraph). In other words, it is desirable for the pores of the mandrel 2 to be sufficiently small that the gas can enter the pores but the composition 14 cannot. Since the composition 14 cannot enter the micropores of the mandrel 2, the mandrel 2 cannot absorb the composition 14, and the mandrel 2 cannot be said to necessarily absorb the composition 14.

In conclusion, *Parsons* does not expressly or inherently teach the pores, absorbing layer and absorbent material of independent claims 64 and 70. Therefore, *Parsons* cannot anticipate independent claims 64 and 70. Dependent claims 65, 66, 71, and 72 are also not anticipated because they depend from independent claims 64 and 70.

Claims 76-80 were rejected under 35 U.S.C. §102(e) as being anticipated by *Heller* (U.S. Publication 20030215564). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Independent claim 76 recites a support member having first and second members, wherein the first member contacts a first end of the stent and the second member contacts a second end of the stent.

*Heller* does not disclose two members contacting the two ends of the stent, respectively. In *Heller*, the stent is mounted on a single member (i.e., the balloon 304 shown in Figure 7). Accordingly, *Heller* cannot anticipate independent claim 76. Dependent claims 77-80 are also not anticipated because they depend from independent claim 76.

Additionally or alternatively, claim 76 recites that “the first or second member is made from an absorbent material capable of at least partially absorbing at least some of the coating composition that comes into contact with the first or second member during the application of the coating composition.”

The Examiner did not contend that *Heller* expressly teaches the first or second member made from an absorbent material capable of absorbing a coating composition. Instead she contended that the *Heller* discloses that a tubular sleeve 134, on which a stent is mounted during coating, may be made from silicone rubber and natural rubber. The

Examiner further contended that one of ordinary skill in the art would have recognized that silicone rubber or natural rubber is inherently capable of absorbing a coating solution.

Applicants respectfully disagree with the contention that silicone rubber or natural rubber is inherently capable of absorbing a coating composition. If the Examiner maintains this rejection, Applicants respectfully request that the Examiner provide evidence supporting her contention.

Additionally, the Examiner merely asserted that silicone rubber or natural rubber is inherently capable of absorbing a coating solution, but provided no evidence to support the assertion. If this rejection is maintained on the same ground, Applicants respectfully request that the Examiner provide evidence showing that one of ordinary skill in the art would have recognized that silicone rubber or natural rubber is inherently capable of absorbing a coating solution. *In re Sang-Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2d 1430 (if the Examiner's assertion of common knowledge is challenged by the applicant, she is required to support the assertion with evidence).

In conclusion, the Examiner has not established that *Heller* teaches a first or second member made from an absorbent material capable of absorbing a coating composition. Therefore, *Heller* cannot anticipate independent claim 76. Dependent claims 77-80 are also not anticipated because they depend from independent claim 76.

#### **Rejections under 35 U.S.C. §103(a)**

Claims 19-23, 30-33, and 35-38 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Taylor* in view of *Castro* (U.S. Patent 6,395,326). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

The rejection is improper, because *Castro* is not qualified as §103(a) prior art under 35 U.S.C. §103(c). *Castro* may be prior art to the claimed invention only under 35 U.S.C. §102(e). But both the claimed invention and *Castro* were, when the claimed invention was made, subject to an obligation of assignment to the same assignee, Advanced Cardiovascular Systems, Inc., a California corporation (see attached Statement of Common Ownership). Therefore, *Castro* cannot be used in an obviousness rejection of the claimed invention.

Claims 40-46 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Heller* in view of *Murayama* (U.S. Patent 5,229,211). The Examiner rejected claim 46 but did not explain why claim 46 was rejected. Applicants assume that claim 46 was mistakenly included in this rejection. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 40-45.

As discussed above, *Heller* does not teach or suggest the “porous surface” limitation of claim 39, from which claims 40-45 depend. In addition, the Examiner did not allege that *Murayama* teaches or suggests this limitation. Therefore, the Examiner has not established that the cited references teach or suggest every limitation of each of claims 40-45. Consequently, the cited references do not render claims 40-45 obvious.

Claim 46 was rejected under 35 U.S.C. §103(a) as being unpatentable over *Heller* in view of *Ding* (U.S. Patent 6,346,856). For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

As discussed above, *Heller* does not teach or suggest the “porous surface” limitation of claim 39, from which claim 46 depend. In addition, the Examiner did not allege that *Ding* teaches or suggests this limitation. Therefore, the Examiner has not established that the cited references teach or suggest every limitation of claim 46. Consequently, the cited references do not render claim 46 obvious.

Additionally or alternatively, the Examiner contended that Figures 1a and 1b of *Ding* show “inwardly tapered ends that penetrate at least partially in the first and second ends of the stent.” Applicants respectfully disagree. Figure 2b of the present application illustrates an embodiment of the inwardly tapered ends (30, 36) according to the claimed invention, where the inwardly tapered ends (30, 36) face each other. In *Ding*, the ends of the catheter balloon are outwardly tapered as they face away from each other. Therefore, the Examiner has not established that the cited references disclose the “inwardly tapered ends” of claim 46. Consequently, the cited references do not render claim 46 obvious.

Claim 54 was rejected under 35 U.S.C. §103(a) as being unpatentable over *Moein*. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.



The rejection is improper, because *Moein* is not qualified as §103(a) prior art under 35 U.S.C. §103(c). *Moein* may be prior art to the claimed invention only under 35 U.S.C. §102(e). But both the claimed invention and *Moein* were, when the claimed invention was made, subject to an obligation of assignment to the same assignee, Advanced Cardiovascular Systems, Inc., a California corporation (see attached Statement of Common Ownership). Therefore, *Moein* cannot be used in an obviousness rejection.

Additionally, the attached §1.131 Declaration establishes invention by Applicants prior to the filing date of *Moein*. Therefore, *Moein* is not prior art to the claimed invention under 35 U.S.C. §102(e).

Claims 67-69 and 73-75 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Parsons* in view of *Moein*. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

The rejection is improper, because, as stated above, *Moein* cannot be used in an obviousness rejection of the claimed invention.

Claims 59-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over *Heller* in view of *Ding*. For the following reasons, Applicants respectfully request reconsideration and withdrawal of the rejection.

Independent claim 59 recites a first member of the mounting assembly supporting a first end of the stent, and a second member of the mounting assembly supporting a second end of the stent.

Contrary to the Examiner's contention, *Heller* does not disclose two members of a mounting assembly that support the two ends of a stent, respectively. In *Heller*, the stent is mounted on a single member (i.e., the balloon 304 shown in Figure 7). Therefore, the Examiner has not established that the cited references teach or suggest the first and second members of claim 59. Accordingly, the Examiner has not established that the cited references render claim 59 obvious. Claims 60-63 are also not obvious because they depend from claim 59.

Additionally or alternatively, the cited references do not disclose the limitation of claim 59 that "the first or second member includes a layer disposed on a surface of the first or

second member, wherein the layer absorbs at least some of the coating composition that comes into contact with the layer during the application of the coating composition.”

As stated above, the Examiner contended that *Heller* teaches two members of a mounting assembly that support the two ends of a stent. The Examiner also contended that although *Heller* does not teach a layer disposed on a surface of the first or second member, *Ding* discloses such a layer (i.e., the sponge coating composition on the surface of a balloon as described in column 2, lines 59-66). The Examiner further contended that “it would have been obvious to one of ordinary skill in the art to use the teaching of Ding et al. (‘856) in the coating method of Heller et al. (‘564) to remove excess coating solution and minimize the build-up on the stent surface.”

For at least the following two reasons, Applicants respectfully disagree with the Examiner’s contention that “it would have been obvious to one of ordinary skill in the art to use the teaching of Ding et al. (‘856) in the coating method of Heller et al. (‘564).”

First, one of ordinary skill in the art would not use the sponge coating composition of *Ding* “to remove excess coating solution and minimize the build-up on the stent surface.” The sponge coating composition of *Ding* is used for two purposes. In the embodiment shown in Figures 1a and 1b, the voids 10 of the sponge coating 4 are used to accommodate a drug 5 (column 3, lines 38-41). In the embodiments shown in Figures 2a, 2b, and 3, the voids 10 of the sponge coating 4 are used as a passageway for a drug 5 stored inside the balloon 3 to pass through the sponge coating 4 into the afflicted tissue 9 (column 4, lines 1-9 and 33-38). The Examiner’s suggested use of the sponge coating 4 is contrary to these stated uses. In the embodiment shown in Figures 1a and 1b, the voids 10 of the sponge coating 4 are filled with the drug 5 and therefore cannot absorb excess coating from a stent surface. In the embodiments shown in Figures 2a, 2b, and 3, one of ordinary skill in the art would not use the voids 10 to absorb excess coating from a stent surface, because the voids 10 must be left empty so that the drug 5 can pass through the sponge coating 4. Therefore, the teaching of *Ding* would not have motivated one of ordinary skill in the art to use the sponge coating composition to remove excess coating from a stent surface during the application of the coating composition.

Second, the Examiner has not established that the prior art suggests using the sponge coating of *Ding* “to remove excess coating solution and minimize the build-up on the stent

surface.” A proper analysis under §103(a) requires, *inter alia*, consideration of whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed invention. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). The suggestion must be found in the prior art, not in the applicant’s disclosure. *Id.* Applicants respectfully submit that the Examiner has failed to point out where in the prior art exists the suggestion to combine the teachings of the cited references. The Examiner contended that “it would have been obvious to one of ordinary skill in the art to use the teaching of Ding et al. (‘856) in the coating method of Heller et al. (‘564) to remove excess coating solution and minimize the build-up on the stent surface.” However, the Examiner failed to show where and how the prior art provides this suggestion. Accordingly, the Examiner has not established that the cited references render claim 59 obvious. Claims 60-63 are also not obvious because they depend from claim 59.

In light of the foregoing remarks, this application is considered to be in condition for allowance, and early passage of this case to issue is respectfully requested. If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 07-1850.

Respectfully submitted,

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